UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,959	02/26/2002	Seah H. Lim	010.00131	5006

7590 01/16/2007

Kathy Smith Dias Esq
Heslin Rothenberg Farley & Mesiti P C
5 Columbia Circle
Albany, NY 12203-5160

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/082,959	LIM ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: Appendix I

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2006 are acknowledged and have been entered. Claim 6 has been amended. An action on the RCE follows.

2 Claims 6 is pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC 112

4. Claim 6 is rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite in the use of protein designation "human sperm protein 17 (SP17)" as the sole means of identifying the claimed protein which is specifically recognized by an isolated cytotoxic T cell because although the specification refers to Lea et al for identification of the protein, the claim is not limited to the protein of Lea et al. Amendment of the claim to include identifiers which unambiguously define the claimed protein to which is specifically recognized by an isolated cytotoxic T cell is required.

Some of Applicant's arguments are relevant to the instant rejection.

Applicant argues that claim 6 is amended to clarify that the isolated cytotoxic cell of the invention specifically recognizes human SP-17 as opposed to Sp-17 in

other species. Applicant argues that the amino acid sequence of human SP-17 was reported by Lea et al and an entry of the information in the NCB1 database as accession number Q155056 made in 1996. Thus, based on the availability of the amino acid sequence of human Sp-17 as of the filing date of the present application, one of skill in attempting to generate a cytotoxic cell directed to SP-17 in accordance with Applicant's invention would have had a definite comprehension of the structure of that antigen. Applicant argues that to further limit the antigen to a specific amino acid sequence, for example, the sequence of Lea et al, would not preclude the use by potential infringers of later identified polymorphisms of Sp-17 that occur in the population and Applicant's patent protection would thereby be rendered meaningless.

The argument has been considered but has not been found persuasive because although the claim is now limited to human sperm protein 17, the claim is not limited to the sperm protein 17 of Lea et al and it cannot be determined from the information in the specification and claims as originally filed, or from the art of record which human sperm protein 17 is being claimed. Although Applicant points to the NCBI database accession number Q155056 as disclosing the sequence of human SP-17 of Lea et al, a review of the NCBI databases did not reveal any hits for accession number Q155056 (see attached Appendix I). Further, even if the sequence was publicly available in the database, accession numbers are not considered to be unique identifiers of any protein. In particular, these identifiers do not satisfy the requirement for unique identifiers because accession numbers can be modified, changed, and/or updated, and thus the cited sequence may vary or change over time and identifying a molecule by accession number does not provide a reliable unique identifier. Further, it is noted, as previously set forth given that

the specification as currently constituted does not refer to NCBI database accession number Q155056, even if the specification includes a reference that is incorporated by reference which includes information drawn to Q155056, mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure. Thus, the metes and bounds of the patent protection sought remain undefined, especially in view of Ms. Smith Dias' statement that the invention is meant to include later identified polymorphisms of SP17 and apparently any variants thereof, including splice variants. Thus, it appears that Applicant's apparent refusal to unambiguously identify the antigen which is recognized by the isolated cytotoxic T cell is an attempt to broaden the scope of the originally claimed invention wherein it does not appear that variants or later identified polymorphisms were ever contemplated in the specification and claims as originally filed. Applicant is reminded that the patent protection is not awarded for molecules that were unknown at the time the invention was filed. Applicant is required to teach how to make and use the claimed invention at the time the application is filed.

The arguments have been considered but have not been found persuasive and the rejection stands.

New Grounds of Rejection

Claim Rejections - 35 USC 112

5. Claim 6 is rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 6 is drawn a to an isolated cytotoxic T cell which specifically recognizes human sperm protein 17. The specification teaches that SP17 is a protein

of apparent molecular mass of 24.5 kDa that is involved in acrosome reactions in spermatozoa. (Lea et al. 1997) (para 0014 of the published application).

In the paper filed March 20, 2006, Applicant points to Lea et al, 1996 and states that "The amino acid sequence of several orthologues of Sp17 are known, including, mouse, rabbit, baboon and human. Though polymorphisms may exist across species or within populations, one of skill in the art would immediately recognize that a protein designated as Sp17 unambiguously refers to a tissue-specific antigen having a known amino acid sequence". It is here noted, for Applicant's information, that SP17 is in fact not a tissue-specific antigen given the teaching of Buchli et al (BBA, 2002, 1578:29-42) who specifically teach that SP17 expression is not testis-specific (see abstract).

Further, in the paper filed October 25, 2006, Applicant argues that "to further limit the antigen to a specific amino acid sequence, for example, the sequence of Lea et al, would not preclude the use by potential infringers of later identified polymorphisms of Sp-17 that occur in the population". Given that Applicant admits that polymorphisms may exist within populations, given Applicant's clear intention to interpret the term "human sperm protein 17 (SP17)" to include later identified polymorphisms, despite the fact that this interpretation was never contemplated in the claims or specification as originally filed, it is clear that although one would recognize the SP17 of Lea et al, one would clearly not recognize SP17's that do contain polymorphisms and that therefore do not have a known amino acid sequence and the specification lacks adequate written description for the broadly claimed protein which is recognized by an isolated cytotoxic T-cell.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. This conclusion is especially critical to the instant invention given that Applicant specifically states that it is intended that the term human sperm protein 17 be inclusive of "later identified polymorphisms".

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a protein product itself logically cannot adequately describe a cytotoxic T cell that specifically recognizes that product.

Thus, the instant specification may provide an adequate written description of the SP17 that is specifically recognized by an isolated cytotoxic T cell, per Lilly by structurally describing a representative number of SP17s that are specifically recognized by an isolated cytotoxic T cell or by describing "structural features

common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the SP17s that are specifically recognized by an isolated cytotoxic T cell in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any SP17s that are specifically recognized by an isolated cytotoxic T cell, nor does the specification provide any partial structure of such SP17s that are specifically recognized by an isolated cytotoxic T cell, nor any physical or chemical characteristics of the SP17s that are specifically recognized by an isolated cytotoxic T cell nor any functional characteristics coupled with a known or disclosed correlation between structure and function other than the SP17 of Lea et al. Although the specification discloses a SP17 of Lea et al that is specifically recognized by an isolated cytotoxic T cell single, this does not provide a description of the SP17s that are specifically recognized by an isolated cytotoxic T cell that would satisfy the standard set out in Enzo.

The specification also fails to describe the SP17s that are specifically recognized by an isolated cytotoxic T cell by the test set out in Lilly. The specification describes only a single SP17 that is specifically recognized by an isolated cytotoxic T cell. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does

not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the SP17s that are specifically recognized by an isolated cytotoxic T cell that are required to practice the claimed invention. Since the specification fails to adequately describe the protein product which is recognized by an isolated cytotoxic T cell, it also fails to adequately describe the cytotoxic T-cell claimed.

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898.. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
January 3, 2007

Appendix 1

NCBI

Entrez, The Life Sciences Search Engine

HOME | SEARCH | SITE MAP | PubMed | All Databases | Human Genome | GenBank | Map Viewer | BLA

Search across databases Q155056 GO CLEAR Help

none	**PubMed:** biomedical literature citations and abstracts		none	**Books:** online books	
none	**PubMed Central:** free, full text journal articles		none	**OMIM:** online Mendelian Inheritance in Man	
none	**Site Search:** NCBI web and FTP sites		none	**OMIA:** Online Mendelian Inheritance in Animals	
none	**Nucleotide:** sequence database (includes GenBank)		none	**UniGene:** gene-oriented clusters of transcript sequences	
none	**Protein:** sequence database		none	**CDD:** conserved protein domain database	
none	**Genome:** whole genome sequences		none	**3D Domains:** domains from Entrez Structure	
none	**Structure:** three-dimensional macromolecular structures		none	**UniSTS:** markers and mapping data	
none	**Taxonomy:** organisms in GenBank		none	**PopSet:** population study data sets	
none	**SNP:** single nucleotide polymorphism		none	**GEO Profiles:** expression and molecular abundance profiles	
none	**Gene:** gene-centered information		none	**GEO DataSets:** experimental sets of GEO data	
none	**HomoloGene:** eukaryotic homology groups		none	**Cancer Chromosomes:** cytogenetic databases	
none	**PubChem Compound:** unique small molecule chemical structures		none	**PubChem BioAssay:** bioactivity screens of chemical substances	
none	**PubChem Substance:** deposited chemical substance records		none	**GENSAT:** gene expression atlas of mouse central nervous system	
none	**Genome Project:** genome project information		none	**Probe:** sequence-specific reagents	
none	**Gap:** genotype and phenotype				
none	**Journals:** detailed information *about* the journals indexed in PubMed and other Entrez databases		none	**MeSH:** detailed information about NLM's controlled vocabulary	
none	**NLM Catalog:** catalog of books, journals, and audiovisuals in the NLM collections				

- Result counts displayed in gray indicate one or more terms not found